DARPA-Funded Human Subjects Research

Guidance for SBIRs and STTRs

Definition and Regulations

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) must abide by the same regulations and guidelines for research involving human subjects as regularly funded contracts.

HUMAN SUBJECTS RESEARCH

"Human use" protocols apply to all research that meets either of the following criteria:

1) Any research involving an INTERVENTION or an INTERACTION with a living person that would not be occurring or would be occurring in some other fashion but for this research.
2) Any research involving data/information/specimens collected originally from people (broadcast video, web-use logs, etc.) in which the identity of the subject is known, or the identity may be readily ascertained from the information.

REGULATIONS

- *The Common Rule*

  Title 32, Code of Federal Regulations (CFR) Part 219, "Protection of Human Subjects," current edition
  http://www.dtic.mil/biosys/downloads/32cfr219.pdf

- *DoD Directive 3216.02*

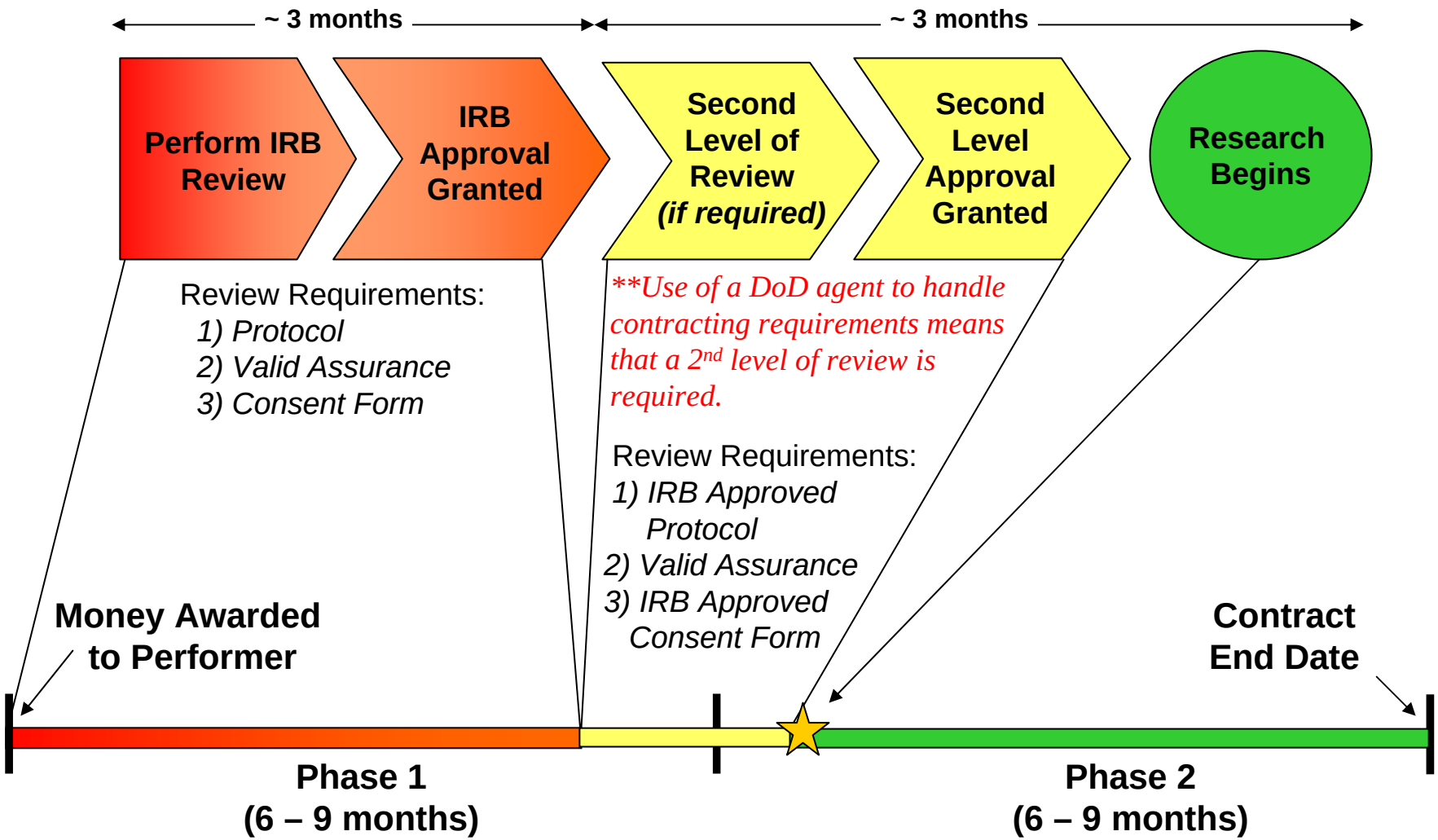
  Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," April 27, 2007
  http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

Additional Information

- Recommend proposing human use research to be conducted in Phase 2; therefore ensuring enough time to prepare and submit Institutional Review Board (IRB) documents and obtain a valid assurance in Phase 1 to not delay start of work in Phase 2.
- If DARPA PM has chosen an approved DoD Agent (AMCOM, ONR, AFOSR, etc.) to award the money to the performer, be aware that a 2nd level review must occur prior to start of research. Depending on agent chosen, the review could take a couple months. Better to start on human use documentation ASAP.
- Recommend use of a Commercial IRB to review human use portion of research.
  - Extensive list of IRBs maintained by AdvaMed:

    http://www.advamed.org/MemberPortal/Issues/FDA/irbs.htm
  - *Average Turnaround Time*: Unconditional approval and/or decision documents returned in a week
  - *Average Costs*: Initial $900-$2750; Continuing $400-$2750. Additional fees may apply depending on additional research sites, investigators, etc.
- DARPA will pay for the costs of using a commercial IRB if included in the proposed budget.
- ***Provide ample time to complete the entire approval process!***

The Approval Process and Timeline



Definitions

- **Assurance** – A formal written document issued by a federal department ensuring compliance with necessary regulations governing human subject research and describing those proceedings through which compliance will be achieved. Examples: Federal Wide Assurance (FWA) through DHHS or Single Project Assurance (SPA) through DoD.
- **Common Rule** – The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is 32 CFR 219.
- **DARPA Agent** – DARPA executes its programs through the Military Departments and other US Government agencies, called Agents, and where appropriate demonstrates technical feasibility and defense utility in joint experiments and demonstrations with these Agents. DARPA Agents perform functions such as award and administration of contracts, oversight of technical efforts, and various support functions. In addition, they may actively participate in the development of technology.
- **Informed Consent** – The legally effective informed consent of the human subject or the human subject's legally authorized representative prior to that individual's participation in human subject research.
- **Institutional Review Board (IRB)** – A committee designated by an institution to review, approve, and conduct periodic monitoring of research involving human subjects. IRBs assume oversight responsibility for protecting the rights of human subjects.
- **Protocol** - A comprehensive, detailed and specific plan of action for execution of human subjects research. A protocol would includes such items but not limited to: Objectives, Research Design, Population, Recruitment Process, Data Collection, and Analyses.